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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,934	12/11/2003	Howard Allen Ketelson	2437 US	7305
26356	7590	06/16/2005	EXAMINER	
ALCON RESEARCH, LTD. R&D COUNSEL, Q-148 6201 SOUTH FREEWAY FORT WORTH, TX 76134-2099			PEZZUTO, HELEN LEE	
			ART UNIT	PAPER NUMBER
			1713	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/732,934

Applicant(s)

KETELSON, HOWARD ALLEN

Examiner

Helen L. Pezzuto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-19 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 5-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election of Group I, claims 5-16 in the reply filed on 6/1/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/1/05.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohanon et al. (J. Biomater. Sci Polymer Edn.,

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1996, 8(1), 19-39) or Uchida et al. (Biomaterials, 21 (2000), 923-929), or WO 02/30571.

Bohanon et al. (J. Biomater Sci polymer Edn) disclose the surface analysis of adsorption of proteins and cells on oxidized silicon and plasma treated polystyrene substrate surfaces modified/grafted with NIPAM polymers, resulting in the prevention of protein adsorption on said modified surfaces. Specifically, an ultra thin layer of PNIPAM was found to be effective in near complete inhibition of fibrinogen and RNase adsorption on the PNIPAM-grafted surfaces. Steric stabilization has been suggested as a factor in the capability of NIPAM polymer in preventing protein adsorption. The article further discuss the potential of using PNIPAM modified surfaces as means in protein adsorption control in many areas of medical application, including application in bimolecular materials, biosensors, and neurochip.

Similarly, Uchida et al. studied the blood platelet adhesion on PIPAAm-grafted cell culture surfaces, wherein prevention of platelet adhesion was found on these modified surfaces at below LCST. The authors suggest using PIPAAm-grafted surfaces as means in regulating blood-platelet interactions via temperature control of PIPAAm.

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WO 02/30571 discloses a method of treating various surfaces using surface adsorbing polymers including N-isopropylacrylamide polymer and copolymers, which serves to decrease adsorption of organic materials (i.e. proteins, polypeptides) onto said surfaces. Suitable surfaces include polymethyl methacrylate, polydimethylsiloxanes, polyurethane which falls within the scope of the instant contact lenses and medical devices.

Prior art discussed are directed to PNIPAM-grafted surfaces and the capability of such surfaces in protein adsorption inhibition, in vivo and in vitro. Such capability would meet the instant requirement of prolong exposures to proteins. The references are silent regarding the medical device expressed in claim 8, in particular contact lens. The examiner is of the position that the ability of NIPAM in protein adsorption is an inherent property/characteristic of the polymer itself, as implicitly taught in the references. The ability in preventing protein adsorption lies in the property of the surface-modified layer. So long as a homogeneous layer of PNIPAM is distributed (i.e. grafted) onto a given surface, its ability to inhibit protein adsorption is expected. In

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any event, in light of the teaching that surfaces grafted with PNIPAM have the capability of preventing protein adsorption, and that such finding have potential in biomedical applications. It would have been obvious to one skilled in the art to modify medical device surfaces such as contact lens, by grafting PNIPAM onto said surfaces, motivated by the reasonable expectation of success in preventing protein adsorption onto said surfaces as suggested. Thus, rendering obvious the instant invention.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Applicant's amendment filed on 2/7/05 necessitated the new ground(s) of rejection presented in this Office action.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen L. Pezzuto whose telephone number is (571) 272-1108. The examiner can normally be reached on 8 AM to 4 PM, Monday thru Friday.

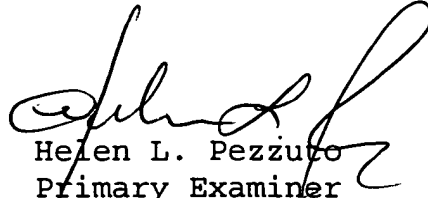
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Helen L. Pezzuto
Primary Examiner
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hlp